Amendments to the Claims

Listing of the Claims

This listing of claims will replace all prior versions, and listings, of claims in the application:

Claims 1 – 10 (cancelled).

11. (Currently Amended) A dry powder aerosol composition for pulmonary or nasal delivery comprising spherically shaped aggregates ~~of~~ formed from spray-drying aqueous dispersions of nanoparticulate drug particles, wherein:

(a) the aqueous dispersions of nanoparticulate drug particles:

(i) comprise a poorly soluble crystalline drug, wherein by "poorly soluble" it is meant that the drug has a solubility in at least one liquid dispersion medium of less than about 10 mg/ml,

(ii) have an effective average particle size of less than about 1000 nm, meaning at least 50% of the drug particles have a particle size of less than about 1000 nm, and

(iii) have a surface modifier adsorbed on the surface thereof; and

(b) the aggregates of such spray-dried drug particle dispersions are less than or equal to about 100 microns in diameter; and

(c) such aggregates return to nanoparticulate drug particle dispersions upon reconstitution in ~~a~~ **an aqueous** liquid medium.

12. (Original) The aerosol composition of claim 11 further comprising a diluent.

13. (Original) The aerosol composition of claim 12, wherein essentially every diluent particle comprises at least one embedded nanoparticulate drug particle having a surface modifier adhered to the surface of the drug particle.

14. (Original) The aerosol composition of claim 11, wherein the drug is selected from the group consisting of proteins, peptides, elastase inhibitors, analgesics, cystic-fibrosis therapies, asthma therapies, emphysema therapies, respiratory distress syndrome therapies, chronic bronchitis therapies, chronic obstructive pulmonary disease

therapies, organ-transplant rejection therapies, therapies for tuberculosis and other infections of the lung, fungal infection therapies, and respiratory illness therapies associated with acquired immune deficiency syndrome, an oncology drug, an anti-emetic, and a cardiovascular agent.

15. (Previously Presented) The aerosol composition of claim 11, wherein the nanoparticulate drug particles have an effective average particle size of less than about 400 nm.

16. (Original) The aerosol composition of claim 11, wherein the aerosol comprises a concentration of a drug in an amount of from about 0.05 mg/g up to about 900 mg/g.

17. (Original) The aerosol composition of claim 16, wherein the aerosol comprises a concentration of a drug selected from the group consisting of about 10 mg/g or more, about 100 mg/g or more, about 200 mg/g or more, about 400 mg/g or more, about 600 mg/g or more, and about 900 mg/g.

18. (Previously Presented) The aerosol composition of claim 11, wherein the aggregates of the nanoparticulate drug particles have a mass median aerodynamic diameter of about 2 to about 10 microns.

19. (Previously Presented) The aerosol composition of claim 18, wherein the aggregates of the nanoparticulate drug particles have a mass median aerodynamic diameter of about 2 to about 6 microns.

20. (Previously Presented) The aerosol composition of claim 11, wherein the aggregates of the nanoparticulate drug particles have a mass median aerodynamic diameter of less than about 2 microns.

21. (Previously Presented) The aerosol composition of claim 11, wherein the aggregates of the nanoparticulate drug particles have a mass median aerodynamic diameter of about 5 to about 100 μm.

22. (Previously Presented) The aerosol composition of claim 21, wherein the aggregates of the nanoparticulate drug particles have a mass median aerodynamic diameter of about 30 to about 60 μm.

23. (Currently Amended) A dry powder aerosol composition for pulmonary or nasal delivery comprising spherically shaped aggregates formed from freeze-drying aqueous dispersions of nanoparticulate drug particles, wherein:

(a) the aggregates of such freeze-dried drug particle dispersions are less than or equal to about 100 microns in diameter;

(b) the aqueous dispersions of nanoparticulate drug particles:

(i) comprise a poorly soluble crystalline drug, wherein by "poorly soluble" it is meant that the drug has a solubility in at least one liquid dispersion medium of less than about 10 mg/ml,

(ii) have an effective average particle size of less than about 1000 nm, meaning at least 50% of the drug particles have a particle size of less than about 1000 nm, and

(iii) have a surface modifier adsorbed on the surface thereof; and

(c) such aggregates return to nanoparticulatre drug particle dispersions upon reconstitution in ~~a~~ **an aqueous** liquid medium.

24. (Original) The aerosol composition of claim 23, further comprising a diluent.

25. (Previously Presented) The aerosol composition of claim 23, wherein the drug is selected from the group consisting of proteins, peptides, elastase inhibitors, analgesics, cystic-fibrosis therapies, asthma therapies, emphysema therapies, respiratory distress syndrome therapies, chronic bronchitis therapies, chronic obstructive pulmonary disease therapies, organ-transplant rejection therapies, therapies for tuberculosis and other infections of the lung, fungal infection therapies, and respiratory illness therapies associated with acquired immune deficiency syndrome, an oncology drug, an anti-emetic, and a cardiovascular agent.

26. (Previously Presented) The aerosol composition of claim 23, wherein the nanoparticulate drug particles have an effective average particle size of less than about 400 nm.

27. (Original) The aerosol composition of claim 23, wherein the aerosol comprises a concentration of a drug in an amount of from about 0.05 mg/g up to about 900 mg/g.

28. (Original) The aerosol composition of claim 27, wherein the aerosol comprises a concentration of a drug selected from the group consisting of about 10 mg/g or more, about 100 mg/g or more, about 200 mg/g or more, about 400 mg/g or more, about 600 mg/g or more, and about 900 mg/g.

29. (Previously Presented) The aerosol composition of claim 23, wherein the aggregates of the nanoparticulate drug particles have a mass median aerodynamic diameter of about 2 to about 10 microns.

30. (Previously Presented) The aerosol composition of claim 29, wherein the aggregates of the nanoparticulate drug particles have a mass median aerodynamic diameter of about 2 to about 6 microns.

31. (Previously Presented) The aerosol composition of claim 23, wherein the aggregates of the nanoparticulate drug particles have a mass median aerodynamic diameter of less than about 2 microns.

32. (Previously Presented) The aerosol composition of claim 23, wherein the aggregates of the nanoparticulate drug particles have a mass median aerodynamic diameter of about 5 to about 100 μm.

33. (Previously Presented) The aerosol composition of claim 32, wherein the aggregates of the nanoparticulate drug particles have a mass median aerodynamic diameter of about 30 to about 60 μm.

34. (Original) The aerosol composition of claim 23, further comprising spray-dried nanoparticulate drug powder, wherein the drug of the freeze-dried nanoparticulate drug powder is either the same or different from the drug of the spray-dried nanoparticulate drug powder.

35. (Currently Amended) A dry powder nanoparticulate aerosol composition for use in a propellant-based pMDI comprising

(a) spherically shaped aggregates of ~~a~~ nanoparticulate poorly soluble crystalline drug particles, wherein by "poorly soluble" it is meant that the drug has a solubility in at least one liquid dispersion medium of less than about 10 mg/ml, wherein the aggregates are less than or equal to about 100 microns in diameter, wherein such aggregates return to nanoparticulate drug particles upon reconstitution in ~~a~~ **an aqueous** liquid medium, and wherein the drug particles:

(i) have a surface modifier adsorbed on the surface thereof, and

(ii) have an effective average particle size of less than about 1000 nm, meaning at least 50% of the drug particles have a particle size of less than about 1000 nm, and

(b) a non-aqueous propellant.

36. (Original) The aerosol composition of claim 35, wherein the propellant is a non-CFC propellant.

Claims 37 – 39. (Cancelled)

40. (Currently Amended) A method of making a dry powder nanoparticulate drug composition comprising:

(a) forming an aqueous nanoparticulate dispersion of a poorly soluble drug, wherein:

(i) the dispersion comprises poorly soluble crystalline drug particles and a surface modifier adsorbed on the surface thereof, wherein by "poorly soluble" it is meant that the drug has a solubility in the liquid dispersion medium of less than about 10 mg/ml, and

(ii) the drug particles have an effective average particle size of less than about 1000 nm, meaning at least 50% of the drug particles have a particle size of less than about 1000 nm; and

(b) spray-drying the nanoparticulate dispersion to form a dry powder of spherically shaped aggregates of the nanoparticulate drug and surface modifier particles, wherein the aggregates have a diameter of less than or

equal to about 100 microns, and wherein such aggregates return to a nanoparticulate drug dispersion upon reconstitution in ~~a~~ **an aqueous** liquid medium.

41. (Original) The method of claim 40, further comprising adding a diluent to the nanoparticulate dispersion prior to spray-drying, wherein following spray-drying essentially every diluent particle contains at least one embedded drug particle and a surface modifier.

42. (Currently Amended) A method of making a dry powder nanoparticulate drug aerosol formulation comprising:

(a) milling under non-pressurized conditions in a non-aqueous medium having a high boiling point a dispersion comprising the following:

(i) a poorly soluble crystalline drug, wherein by "poorly soluble" it is meant that the drug has a solubility in the non-aqueous medium of less than about 10 mg/ml, and

(ii) a surface modifier, to obtain a nanoparticulate drug composition having an effective average particle size of less than about 1000 nm, meaning at least 50% of the drug particles have a particle size of less than about 1000 nm, and

(b) evaporating the non-aqueous medium to obtain a dry powder of spherically shaped aggregates of drug and surface modifier particles, wherein the aggregates have a diameter of less than or equal to about 100 microns, and wherein such aggregates return to nanoparticulate drug particle dispersions upon reconstitution in ~~a~~ **an aqueous** liquid medium.

43. (Currently Amended) A method of making an aerosol composition comprising:

(a) milling under pressurized conditions in a non-aqueous medium a dispersion comprising the following:

(i) a poorly soluble crystalline drug, wherein by "poorly soluble" it is meant that the drug has a solubility in the non-aqueous dispersion medium of less than about 10 mg/ml, and

(ii) a surface modifier, to obtain a drug having an effective average particle size of less than about 1000 nm, meaning at least 50% of the drug particles have a particle size of less than about 1000 nm;

(b) evaporating the non-aqueous medium to obtain a dry powder of spherically shaped aggregates of drug and surface modifier particles, wherein the aggregates have a diameter of less than or equal to about 100 microns, and wherein such aggregates return to nanoparticulate drug particle dispersions upon reconstitution in ~~a~~ **an aqueous** liquid medium; and

(c) formulating the dry powder spherically shaped aggregates into an aerosol composition.

44. (Currently Amended) A method of making a dry powder nanoparticulate drug composition comprising:

(a) forming an aqueous nanoparticulate dispersion of a poorly soluble drug, wherein:

(i) the dispersion comprises poorly soluble crystalline drug particles, wherein by "poorly soluble" it is meant that the drug has a solubility in the liquid dispersion medium of less than about 10 mg/ml, and wherein the drug particles have an effective average particle size of less than about 1000 nm, meaning at least 50% of the drug particles have a particle size of less than about 1000 nm, and

(ii) a surface modifier adsorbed on the surface thereof; and

(b) freeze-drying the nanoparticulate dispersion to form a dry powder of spherically shaped aggregates of the nanoparticulate drug and surface modifier particles, wherein the aggregates have a diameter of less than or equal to about 100 microns, and wherein such aggregates return to nanoparticulate drug particle dispersions upon reconstitution in ~~a~~ **an aqueous** liquid medium.

45. (Original) The method of claim 44, further comprising adding a diluent to the nanoparticulate dispersion prior to freeze-drying, wherein following freeze-drying

essentially every diluent particle contains at least one embedded drug particle and a surface modifier.

46. (Cancelled).

47. (Original) A method of administering the aerosol of claim 11 to a patient, wherein the aerosol comprises drug at a concentration of 10 mg/g or greater, and wherein the patient delivery time for the aerosol administration is about 15 seconds or less.

48. (Original) A method of administering the aerosol of claim 23 to a patient, wherein the aerosol comprises drug at a concentration of 10 mg/g or greater, and wherein the patient delivery time for the aerosol administration is about 15 seconds or less.

49. (Original) A method of administering the aerosol of claim 35 to a patient, wherein the aerosol comprises drug at a concentration of 10 mg/g or greater, and wherein the patient delivery time for the aerosol administration is about 15 seconds or less.

50. (Cancelled).

51. (Previously Presented) The aerosol composition of claim 11, wherein the nanoparticulate drug particles have an effective average particle size of less than about 300 nm.

52. (Previously Presented) The aerosol composition of claim 11, wherein the nanoparticulate drug particles have an effective average particle size of less than about 250 nm.

53. (Previously Presented) The aerosol composition of claim 11, wherein the nanoparticulate drug particles have an effective average particle size of less than about 100 nm.

54. (Previously Presented) The aerosol composition of claim 11, wherein the nanoparticulate drug particles have an effective average particle size of less than about 50 nm.

55. (Previously Presented) The aerosol composition of claim 23, wherein the nanoparticulate drug particles have an effective average particle size of less than about 300 nm.

56. (Previously Presented) The aerosol composition of claim 23, wherein the nanoparticulate drug particles have an effective average particle size of less than about 250 nm.

57. (Previously Presented) The aerosol composition of claim 23, wherein the nanoparticulate drug particles have an effective average particle size of less than about 100 nm.

58. (Previously Presented) The aerosol composition of claim 23, wherein the nanoparticulate drug particles have an effective average particle size of less than about 50 nm.

59. (Previously Presented) The aerosol composition of claim 11, wherein at least 70% of the drug particles have a particle size of less than about 1000 nm.

60. (Previously Presented) The aerosol composition of claim 11, wherein at least 90% of the drug particles have a particle size of less than about 1000 nm.

61. (Previously Presented) The aerosol composition of claim 23, wherein at least 70% of the drug particles have a particle size of less than about 1000 nm.

62. (Previously Presented) The aerosol composition of claim 23, wherein at least 90% of the drug particles have a particle size of less than about 1000 nm.

63. (Previously Presented) The aerosol composition of claim 35, wherein at least 70% of the drug particles have a particle size of less than about 1000 nm.

64. (Previously Presented) The aerosol composition of claim 35, wherein at least 90% of the drug particles have a particle size of less than about 1000 nm.

65. (Previously Presented) The aerosol composition of claim 42, wherein at least 70% of the drug particles have a particle size of less than about 1000 nm.

66. (Previously Presented) The aerosol composition of claim 42, wherein at least 90% of the drug particles have a particle size of less than about 1000 nm.

67. (Previously Presented) The aerosol composition of claim 43, wherein at least 70% of the drug particles have a particle size of less than about 1000 nm.

68. (Previously Presented) The aerosol composition of claim 43, wherein at least 90% of the drug particles have a particle size of less than about 1000 nm.

69. (Previously Presented) The aerosol composition of claim 44, wherein at least 70% of the drug particles have a particle size of less than about 1000 nm.

70. (Previously Presented) The aerosol composition of claim 44, wherein at least 90% of the drug particles have a particle size of less than about 1000 nm.

71. (Previously Presented) The aerosol composition of claim 19, wherein the drug is selected from the group consisting of proteins, peptides, elastase inhibitors, analgesics, cystic-fibrosis therapies, asthma therapies, emphysema therapies, respiratory distress syndrome therapies, chronic bronchitis therapies, chronic obstructive pulmonary disease therapies, organ-transplant rejection therapies, therapies for tuberculosis and other infections of the lung, fungal infection therapies, and respiratory illness therapies associated with acquired immune deficiency syndrome, an oncology drug, an anti-emetic, and a cardiovascular agent.

72. (Previously Presented) The aerosol composition of claim 19, wherein the nanoparticulate drug particles have an effective average particle size selected from the group consisting of less than about 400 nm, less than about 300 nm, less than about 250 nm, less than about 100 nm, and less than about 50 nm.

73. (Previously Presented) The aerosol composition of claim 20, wherein the drug is selected from the group consisting of proteins, peptides, elastase inhibitors, analgesics, cystic-fibrosis therapies, asthma therapies, emphysema therapies, respiratory distress syndrome therapies, chronic bronchitis therapies, chronic

obstructive pulmonary disease therapies, organ-transplant rejection therapies, therapies for tuberculosis and other infections of the lung, fungal infection therapies, and respiratory illness therapies associated with acquired immune deficiency syndrome, an oncology drug, an anti-emetic, and a cardiovascular agent.

74. (Previously Presented) The aerosol composition of claim 20, wherein the nanoparticulate drug particles have an effective average particle size selected from the group consisting of less than about 400 nm, less than about 300 nm, less than about 250 nm, less than about 100 nm, and less than about 50 nm.

75. (Previously Presented) The aerosol composition of claim 22, wherein the drug is selected from the group consisting of proteins, peptides, elastase inhibitors, analgesics, cystic-fibrosis therapies, asthma therapies, emphysema therapies, respiratory distress syndrome therapies, chronic bronchitis therapies, chronic obstructive pulmonary disease therapies, organ-transplant rejection therapies, therapies for tuberculosis and other infections of the lung, fungal infection therapies, and respiratory illness therapies associated with acquired immune deficiency syndrome, an oncology drug, an anti-emetic, and a cardiovascular agent.

76. (Previously Presented) The aerosol composition of claim 22, wherein the nanoparticulate drug particles have an effective average particle size selected from the group consisting of less than about 400 nm, less than about 300 nm, less than about 250 nm, less than about 100 nm, and less than about 50 nm.

77. (Previously Presented) The aerosol composition of claim 30, wherein the drug is selected from the group consisting of proteins, peptides, elastase inhibitors, analgesics, cystic-fibrosis therapies, asthma therapies, emphysema therapies, respiratory distress syndrome therapies, chronic bronchitis therapies, chronic obstructive pulmonary disease therapies, organ-transplant rejection therapies, therapies for tuberculosis and other infections of the lung, fungal infection therapies, and respiratory illness therapies associated with acquired immune deficiency syndrome, an oncology drug, an anti-emetic, and a cardiovascular agent.

78. (Previously Presented) The aerosol composition of claim 30, wherein the nanoparticulate drug particles have an effective average particle size selected from the

group consisting of less than about 400 nm, less than about 300 nm, less than about 250 nm, less than about 100 nm, and less than about 50 nm.

79. (Previously Presented) The aerosol composition of claim 31, wherein the drug is selected from the group consisting of proteins, peptides, elastase inhibitors, analgesics, cystic-fibrosis therapies, asthma therapies, emphysema therapies, respiratory distress syndrome therapies, chronic bronchitis therapies, chronic obstructive pulmonary disease therapies, organ-transplant rejection therapies, therapies for tuberculosis and other infections of the lung, fungal infection therapies, and respiratory illness therapies associated with acquired immune deficiency syndrome, an oncology drug, an anti-emetic, and a cardiovascular agent.

80. (Previously Presented) The aerosol composition of claim 31, wherein the nanoparticulate drug particles have an effective average particle size selected from the group consisting of less than about 400 nm, less than about 300 nm, less than about 250 nm, less than about 100 nm, and less than about 50 nm.

81. (Previously Presented) The aerosol composition of claim 33, wherein the drug is selected from the group consisting of proteins, peptides, elastase inhibitors, analgesics, cystic-fibrosis therapies, asthma therapies, emphysema therapies, respiratory distress syndrome therapies, chronic bronchitis therapies, chronic obstructive pulmonary disease therapies, organ-transplant rejection therapies, therapies for tuberculosis and other infections of the lung, fungal infection therapies, and respiratory illness therapies associated with acquired immune deficiency syndrome, an oncology drug, an anti-emetic, and a cardiovascular agent.

82. (Previously Presented) The aerosol composition of claim 33, wherein the nanoparticulate drug particles have an effective average particle size selected from the group consisting of less than about 400 nm, less than about 300 nm, less than about 250 nm, less than about 100 nm, and less than about 50 nm.

83. (Previously Presented) The aerosol composition of claim 35, wherein the drug is selected from the group consisting of proteins, peptides, elastase inhibitors, analgesics, cystic-fibrosis therapies, asthma therapies, emphysema therapies, respiratory distress syndrome therapies, chronic bronchitis therapies, chronic

obstructive pulmonary disease therapies, organ-transplant rejection therapies, therapies for tuberculosis and other infections of the lung, fungal infection therapies, and respiratory illness therapies associated with acquired immune deficiency syndrome, an oncology drug, an anti-emetic, and a cardiovascular agent.

84. (Previously Presented) The aerosol composition of claim 35, wherein the nanoparticulate drug particles have an effective average particle size selected from the group consisting of less than about 400 nm, less than about 300 nm, less than about 250 nm, less than about 100 nm, and less than about 50 nm.

85. (Previously Presented) The aerosol composition of claim 35, wherein the aggregates of the nanoparticulate drug particles have a mass median aerodynamic diameter of about 2 to about 10 microns.

86. (Previously Presented) The aerosol composition of claim 85, wherein the aggregates of the nanoparticulate drug particles have a mass median aerodynamic diameter of about 2 to about 6 microns.

87. (Previously Presented) The aerosol composition of claim 35, wherein the aggregates of the nanoparticulate drug particles have a mass median aerodynamic diameter of less than about 2 microns.

88. (Previously Presented) The aerosol composition of claim 35, wherein the aggregates of the nanoparticulate drug particles have a mass median aerodynamic diameter of about 5 to about 100 μm.

89. (Previously Presented) The aerosol composition of claim 88, wherein the aggregates of the nanoparticulate drug particles have a mass median aerodynamic diameter of about 30 to about 60 μm.

90. (Previously Presented) The method of claim 40, wherein the drug is selected from the group consisting of proteins, peptides, elastase inhibitors, analgesics, cystic-fibrosis therapies, asthma therapies, emphysema therapies, respiratory distress syndrome therapies, chronic bronchitis therapies, chronic obstructive pulmonary disease therapies, organ-transplant rejection therapies, therapies for tuberculosis and other

infections of the lung, fungal infection therapies, and respiratory illness therapies associated with acquired immune deficiency syndrome, an oncology drug, an anti-emetic, and a cardiovascular agent.

91. (Previously Presented) The method of claim 40, wherein the nanoparticulate drug particles have an effective average particle size selected from the group consisting of less than about 400 nm, less than about 300 nm, less than about 250 nm, less than about 100 nm, and less than about 50 nm.

92. (Previously Presented) The method of claim 40, wherein the aggregates of the nanoparticulate drug particles have a mass median aerodynamic diameter of about 2 to about 10 microns.

93. (Previously Presented) The method of claim 92, wherein the aggregates of the nanoparticulate drug particles have a mass median aerodynamic diameter of about 2 to about 6 microns.

94. (Previously Presented) The method of claim 40, wherein the aggregates of the nanoparticulate drug particles have a mass median aerodynamic diameter of less than about 2 microns.

95. (Previously Presented) The method of claim 40, wherein the aggregates of the nanoparticulate drug particles have a mass median aerodynamic diameter of about 5 to about 100 μm.

96. (Previously Presented) The method of claim 95, wherein the aggregates of the nanoparticulate drug particles have a mass median aerodynamic diameter of about 30 to about 60 μm.

97. (Previously Presented) The method of claim 42, wherein the drug is selected from the group consisting of proteins, peptides, elastase inhibitors, analgesics, cystic-fibrosis therapies, asthma therapies, emphysema therapies, respiratory distress syndrome therapies, chronic bronchitis therapies, chronic obstructive pulmonary disease therapies, organ-transplant rejection therapies, therapies for tuberculosis and other infections of the lung, fungal infection therapies, and respiratory illness therapies

associated with acquired immune deficiency syndrome, an oncology drug, an anti-emetic, and a cardiovascular agent.

98. (Previously Presented) The method of claim 42, wherein the nanoparticulate drug particles have an effective average particle size selected from the group consisting of less than about 400 nm, less than about 300 nm, less than about 250 nm, less than about 100 nm, and less than about 50 nm.

99. (Previously Presented) The method of claim 42, wherein the aggregates of the nanoparticulate drug particles have a mass median aerodynamic diameter of about 2 to about 10 microns.

100. (Previously Presented) The method of claim 99, wherein the aggregates of the nanoparticulate drug particles have a mass median aerodynamic diameter of about 2 to about 6 microns.

101. (Previously Presented) The method of claim 42, wherein the aggregates of the nanoparticulate drug particles have a mass median aerodynamic diameter of less than about 2 microns.

102. (Previously Presented) The method of claim 42, wherein the aggregates of the nanoparticulate drug particles have a mass median aerodynamic diameter of about 5 to about 100 μm.

103. (Previously Presented) The method of claim 102, wherein the aggregates of the nanoparticulate drug particles have a mass median aerodynamic diameter of about 30 to about 60 μm.

104. (Previously Presented) The method of claim 43, wherein the drug is selected from the group consisting of proteins, peptides, elastase inhibitors, analgesics, cystic-fibrosis therapies, asthma therapies, emphysema therapies, respiratory distress syndrome therapies, chronic bronchitis therapies, chronic obstructive pulmonary disease therapies, organ-transplant rejection therapies, therapies for tuberculosis and other infections of the lung, fungal infection therapies, and respiratory illness therapies

associated with acquired immune deficiency syndrome, an oncology drug, an anti-emetic, and a cardiovascular agent.

105. (Previously Presented) The method of claim 43, wherein the nanoparticulate drug particles have an effective average particle size selected from the group consisting of less than about 400 nm, less than about 300 nm, less than about 250 nm, less than about 100 nm, and less than about 50 nm.

106. (Previously Presented) The method of claim 43, wherein the aggregates of the nanoparticulate drug particles have a mass median aerodynamic diameter of about 2 to about 10 microns.

107. (Previously Presented) The method of claim 106, wherein the aggregates of the nanoparticulate drug particles have a mass median aerodynamic diameter of about 2 to about 6 microns.

108. (Previously Presented) The method of claim 43, wherein the aggregates of the nanoparticulate drug particles have a mass median aerodynamic diameter of less than about 2 microns.

109. (Previously Presented) The method of claim 43, wherein the aggregates of the nanoparticulate drug particles have a mass median aerodynamic diameter of about 5 to about 100 μm.

110. (Previously Presented) The method of claim 109, wherein the aggregates of the nanoparticulate drug particles have a mass median aerodynamic diameter of about 30 to about 60 μm.

111. (Previously Presented) The method of claim 44, wherein the drug is selected from the group consisting of proteins, peptides, elastase inhibitors, analgesics, cystic-fibrosis therapies, asthma therapies, emphysema therapies, respiratory distress syndrome therapies, chronic bronchitis therapies, chronic obstructive pulmonary disease therapies, organ-transplant rejection therapies, therapies for tuberculosis and other infections of the lung, fungal infection therapies, and respiratory illness therapies

associated with acquired immune deficiency syndrome, an oncology drug, an anti-emetic, and a cardiovascular agent.

112. (Previously Presented) The method of claim 44, wherein the nanoparticulate drug particles have an effective average particle size selected from the group consisting of less than about 400 nm, less than about 300 nm, less than about 250 nm, less than about 100 nm, and less than about 50 nm.

113. (Previously Presented) The method of claim 44, wherein the aggregates of the nanoparticulate drug particles have a mass median aerodynamic diameter of about 2 to about 10 microns.

114. (Previously Presented) The method of claim 113, wherein the aggregates of the nanoparticulate drug particles have a mass median aerodynamic diameter of about 2 to about 6 microns.

115. (Previously Presented) The method of claim 44, wherein the aggregates of the nanoparticulate drug particles have a mass median aerodynamic diameter of less than about 2 microns.

116. (Previously Presented) The method of claim 44, wherein the aggregates of the nanoparticulate drug particles have a mass median aerodynamic diameter of about 5 to about 100 μm.

117. (Previously Presented) The method of claim 116, wherein the aggregates of the nanoparticulate drug particles have a mass median aerodynamic diameter of about 30 to about 60 μm.

118. (Previously Presented) The aerosol composition of any one of claims 14, 25, 71, 73, 75, 77, 79, 81, or 83 wherein the drug is selected from the group consisting of a bronchodilator, a corticosteroid, and an anti-fungal.

119. (Previously Presented) The method of any one of claims 90, 97, 104, and 111, wherein the drug is selected from the group consisting of a bronchodilator, a corticosteroid, and an anti-fungal.

120. (Previously Presented) The aerosol composition of claim 14, wherein the drug is selected from the group consisting of beclomethasone dipropionate, naproxen, triamcinolone acetonide, budesonide, and an anti-emetic.

121. (Previously Presented) The aerosol composition of claim 25, wherein the drug is selected from the group consisting of beclomethasone dipropionate, naproxen, triamcinolone acetonide, budesonide, and an anti-emetic.